CHARGE: 502(a)—the name "Multizyme," by which the drug was designated while held for sale, was misleading since it suggested the presence of multiple enzymes in the article as the valuable factor needed in a food supplement for human nutrition, whereas such was not the fact; and, in addition, the leaflets and order cards accompanying the article, while held for sale, contained false and misleading representations that the article would keep the bloodlines of the body clean and so protect one from high blood pressure, and that it would correct the suffering caused by the lack of balance of forces within the body cells; 502(b) (1) and (2)—when shipped, the article failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of contents; 502(e) (2)—when shipped, the article failed to bear a label containing the common or usual name of each active ingredient contained therein; and 502(f) (1)—when shipped, the labeling of the article failed to bear adequate directions for use for the purposes for which it was intended.

DISPOSITION: 12–23–57. Consent—claimed by Lee V. Schneider, Seattle, Wash., and relabeled.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

5449. Posterior pituitary injection. (F.D.C. No. 40200. S. No. 54–805 M.)

QUANTITY: 99 1-cc. vials at Lynwood, Wash.

SHIPPED: 3–19–57, from Philadelphia, Pa., by Lustgarten Laboratories, Inc.

LABEL IN PART: "1 cc Amp. Pituitary Extract 10 U. S. P. Units (Obstetrical) * * * Control No. 020477 * * * Vitamix Corporation Philadelphia, Pa."

RESULTS OF INVESTIGATION: Analysis showed that the potency of the article was less than 0.062 U. S. P. posterior pituitary units per cubic centimeter.

LIBELED: 5–16–57, W. Dist. Wash.

CHARGE: 501(b)—the strength of the article, when shipped, differed from the standard for "Posterior Pituitary Injection" set forth in the United States Pharmacopeia; and 502(a)—the label statement "1 cc Amp. Pituitary Extract 10 U. S. P. Units" was false and misleading as applied to a product, the potency of which is less than 10 U. S. P. posterior pituitary units per cubic centimeter.

DISPOSITION: 7–23–57. Default—destruction.

5450. Progesterone-estrogen. (F.D.C. No. 40367. S. No. 65–086 M.)

QUANTITY: 31 vials in a carton at Columbus, Ohio.

SHIPPED: 4–12–57, from Sarasota, Fla., by Stillco Laboratories.

LABEL IN PART: (Ctn.) "Stillco Laboratories * * * Sarasota, Florida, 35 x 10 cc — Control #956 — Progesterone-Estrogen In Sesame Oil — Intramuscular — Per CC Progesterone USP 25 MGM — Estrogens (95–98% Estrone) 25,000 I. U."

RESULTS OF INVESTIGATION: Analysis showed that the article was an oil solution containing 21.6 percent of the declared amount of estrogens.

LIBELED: 7–2–57, S. Dist. Ohio.

*See also Nos. 5443, 5446.

CHARGE: 501(c)—the strength of the article, when shipped, differed from that which it purported and was represented to possess, namely, 25,000 I. U. estrogens per cubic centimeter; 502(a)—the carton label statement "Per CC * * * Estrogens * * * 25,000 I. U." was false and misleading as applied to the article, which contained 21.6 percent of the declared amount of estrogens; 502(b)(1)—the label of the article failed to bear the name and place of business of the manufacturer, packer, or distributor; 502(b)(2)—the label of the article failed to bear an accurate statement of the quantity of contents; and 502(e)(2)—the label of the article failed to bear the common or usual name of each ingredient.

DISPOSITION: 8–9–57. Default—destruction.

5451. Pyrilamine maleate Prolongsules. (F.D.C. No. 40358. S. No. 41–858 M.)

QUANTITY: 1 drum containing 24,935 capsules, and 238 12-capsule vials at Buffalo, N.Y.

SHIPPED: 3–30–56, from Philadelphia, Pa., by Richlyn Laboratories.

LABEL IN PART: (Drum) "Pyrilamine Maleate Prolongsules * * * Delayed Action, Time Disintegrating Capsules * * * Released Gradually * * * Over A Period of Approximately 8 Hours * * * Each Prolongsule Contains: Pyrilamine Maleate 75 Mgm."

RESULTS OF INVESTIGATION: Analysis showed that the capsules of the article did not allow gradual release of pyrilamine maleate over a period of approximately 8 hours, but, instead, the pyrilamine maleate was released in a much shorter time. Examination showed that the capsules in vials had been repacked from the bulk drum.

LIBELED: 6–27–57, W. Dist. N. Y.

CHARGE: 501(c)—the quality of the article, when shipped, fell below that which it was represented to possess since the active ingredient was not gradually released over an 8-hour period, but was, instead, released in a much shorter time; and 502(a)—the statements in the label which represented and suggested that the active ingredient was gradually released over an 8-hour period were false and misleading.

DISPOSITION: 8–15–57. Default—destruction.

5452. Bennett Arben capsules. (F.D.C. No. 40199. S. Nos. 74–867/70 M.)

QUANTITY: 24,000 capsules of *Formula No. 2*, 23,000 capsules of *Formula No. 6A*, 24,000 capsules of *Formula No. 8A*, and 17,000 capsules of *Formula No. 12A* at Santa Monica, Calif. The capsules were packed in bulk drums.

SHIPPED: On an unknown date, from Miami Beach, Fla., by Arthur Bennett Pharmaceuticals.

LABEL IN PART: "Bennett Arben Capsules Formula No. 2 * * * Amphetamine Sulfate 1.2 mgm. * * * Lot No. 2016," "Bennett Arben Capsules Formula No. 6A * * * Amphetamine Sulfate 1.8 mgm. * * * Lot. No. 3010," "Bennett Arben Capsules Formula No. 8A * * * Amphetamine Sulfate 2.5 mgm. * * * Lot No. 3008," and "Bennett Arben Capsules Formula No. 12A * * * Amphetamine Sulfate 5 mgm. * * * Lot No. 3014."

RESULTS OF INVESTIGATION: Examination showed that the capsules contained the following amounts of amphetamine sulfate per capsule: *Formula No. 2*—2.3 mgs., *Formula No. 6A*—3.3 mgs., *Formula No. 8A*—4.9 mgs., and *Formula No. 12A*—9.8 mgs.